TABLE B3
Summary of the Incidence of Nonneoplastic Lesions in Dietary-Controlled Male Mice in the 2-Year Gavage Study of Chloral Hydrate[a]

	Vehicle Control	25 mg/kg	50 mg/kg	100 mg/kg
Disposition Summary				
Animals initially in study	60	60	60	60
15-Month interim evaluation	12	12	12	12
Early deaths				
Moribund	1	1	1	
Natural deaths	2	3		7
Survivors				
Terminal sacrifice	45	44	47	41
Animals examined microscopically	60	60	60	60
15-Month Interim Evaluation				
Alimentary System				
Liver	(12)	(12)	(12)	(12)
Fatty change, peripheral	1 (8%)	2 (17%)	2 (17%)	
Granuloma, multiple		1 (8%)		
Vacuolization cytoplasmic, centrilobular	1 (8%)	2 (17%)	2 (17%)	
Integumentary System				
Skin		(1)		
Atrophy, focal, hair follicle			1(100%)	
2-Year Study				
Alimentary System				
Esophagus	(47)	(4)	(1)	(48)
Autolysis				2 (4%)
Gallbladder	(46)	(4)	(1)	(43)
Autolysis				1 (2%)
Hemorrhage				1 (2%)
Infiltration cellular, lymphocytic				1 (2%)
Intestine large, cecum	(45)	(4)	(1)	(44)
Autolysis		1 (25%)		2 (5%)
Intestine large, colon	(47)	(4)	(1)	(45)
Autolysis		1 (25%)		2 (4%)
Intestine large, rectum	(47)	(4)	(1)	(46)
Autolysis		1 (25%)		1 (2%)
Intestine small, duodenum	(47)	(4)	(1)	(44)
Autolysis		1 (25%)		2 (5%)
Ulcer		1 (25%)		
Intestine small, ileum	(48)	(4)	(1)	(44)
Autolysis		1 (25%)		2 (5%)
Intestine small, jejunum	(47)	(5)	(1)	(44)
Autolysis				2 (5%)

[a] Number of animals examined microscopically at the site and the number of animals with lesion

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	Vehicle Control	25 mg/kg	50 mg/kg	100 mg/kg
2-Year Study (continued)				
Alimentary System (continued)				
Liver	(48)	(48)	(48)	(48)
Autolysis				1 (2%)
Basophilic focus		1 (2%)	2 (4%)	2 (4%)
Clear cell focus	1 (2%)	1 (2%)	2 (4%)	
Cyst			1 (2%)	1 (2%)
Eosinophilic focus		2 (4%)		
Hyperplasia, focal, ito cell			1 (2%)	
Infarct	1 (2%)			
Infiltration cellular, lymphocytic	1 (2%)	2 (4%)		
Mixed cell focus	1 (2%)			
Necrosis, hepatocyte	1 (2%)			2 (4%)
Necrosis, hepatocyte, midzonal		1 (2%)		
Thrombus				1 (2%)
Vacuolization cytoplasmic, centrilobular		1 (2%)		
Pancreas	(48)	(4)	(1)	(48)
Atrophy, acinar cell	2 (4%)			1 (2%)
Autolysis				2 (4%)
Cyst, duct	1 (2%)			
Dilatation, duct	1 (2%)			
Hyperplasia, lymphoid	1 (2%)			
Salivary glands	(48)	(4)	(1)	(48)
Atrophy				1 (2%)
Autolysis				2 (4%)
Infiltration cellular, lymphocytic	5 (10%)			5 (10%)
Stomach, forestomach	(47)	(5)	(1)	(47)
Autolysis				1 (2%)
Cyst epithelial inclusion				1 (2%)
Hyperplasia, focal		1 (20%)		
Metaplasia, squamous		1 (20%)		
Stomach, glandular	(47)	(5)	(1)	(47)
Autolysis		1 (20%)		2 (4%)
Cyst	1 (2%)			
Hyperkeratosis				1 (2%)
Hyperplasia				1 (2%)
Tongue	(48)	(4)	(1)	(48)
Autolysis				2 (4%)
Cardiovascular System				
Blood vessel	(48)	(4)	(1)	(48)
Arteriosclerosis, artery	2 (4%)			
Autolysis, aorta				1 (2%)
Mineralization, aorta	1 (2%)			
Heart	(48)	(4)	(1)	(48)
Autolysis				1 (2%)
Cardiomyopathy	3 (6%)			2 (4%)

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	Vehicle Control	25 mg/kg	50 mg/kg	100 mg/kg
2-Year Study (continued)				
Endocrine System				
Adrenal gland, cortex	(45)	(4)	(1)	(47)
Autolysis				3 (6%)
Cytoplasmic alteration	1 (2%)			4 (9%)
Hyperplasia	4 (9%)			3 (6%)
Hyperplasia, spindle cell	33 (73%)			24 (51%)
Adrenal gland, medulla	(45)	(4)	(1)	(47)
Autolysis				3 (6%)
Parathyroid gland	(44)	(3)	(47)	
Autolysis				4 (9%)
Cyst				1 (2%)
Thyroid gland	(47)	(4)	(48)	
Autolysis				5 (10%)
Cyst, follicle	3 (6%)			1 (2%)
General Body System				
None				
Genital system				
Coagulating gland	(48)	(4)	(1)	(48)
Autolysis		1 (25%)		3 (6%)
Epididymis	(48)	(4)	(1)	(48)
Autolysis		1 (25%)		4 (8%)
Granuloma sperm				1 (2%)
Inflammation, chronic				1 (2%)
Spermatocele				1 (2%)
Preputial gland	(48)	(4)	(1)	(47)
Atrophy	13 (27%)	2 (50%)		13 (28%)
Autolysis		1 (25%)		3 (6%)
Ectasia, duct	1 (2%)	1 (25%)		1 (2%)
Hyperplasia				1 (2%)
Prostate	(47)	(4)	(1)	(46)
Atrophy				1 (2%)
Autolysis				4 (9%)
Inflammation, acute				1 (2%)
Seminal vesicle	(48)	(4)	(1)	(48)
Autolysis		1 (25%)		4 (8%)
Inflammation, acute				1 (2%)
Testes	(48)	(4)	(1)	(46)
Autolysis		1 (25%)		3 (7%)
Degeneration				1 (2%)
Degeneration, unilateral, seminiferous tubule	1 (2%)			
Mineralization, unilateral, seminiferous tubule	1 (2%)			

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	Vehicle Control	25 mg/kg	50 mg/kg	100 mg/kg
2-Year Study (continued)				
Hematopoietic System				
Bone marrow	(48)	(4)	(1)	(48)
Autolysis				1 (2%)
Hyperplasia	1 (2%)	2 (50%)		2 (4%)
Lymph node, mandibular	(46)	(3)	(1)	(48)
Angiectasis	1 (2%)			
Apoptosis, lymphocyte		1 (33%)		
Atrophy, lymphocyte				1 (2%)
Autolysis				2 (4%)
Lymph node, mesenteric	(44)	(8)	(3)	(48)
Apoptosis, lymphocyte		1 (13%)		
Atrophy	1 (2%)			
Atrophy, lymphocyte				1 (2%)
Autolysis				2 (4%)
Degeneration	4 (9%)	1 (13%)	1 (33%)	3 (6%)
Hyperplasia	2 (5%)			3 (6%)
Pigmentation				1 (2%)
Spleen	(48)	(8)	(4)	(48)
Apoptosis, lymphocyte		1 (13%)		
Atrophy, lymphocyte	1 (2%)			2 (4%)
Autolysis				2 (4%)
Hematopoietic cell proliferation	2 (4%)	4 (50%)	1 (25%)	6 (13%)
Hyperplasia, lymphoid	2 (4%)			1 (2%)
Thymus	(39)	(2)	(1)	(30)
Apoptosis			1 (100%)	
Autolysis				1 (3%)
Cyst				1 (3%)
Integumentary System				
Mammary gland			(2)	
Autolysis				1 (50%)
Skin	(48)	(4)	(1)	(48)
Autolysis				1 (2%)
Musculoskeletal System				
Bone, femur	(48)	(4)	(1)	(48)
Autolysis				1 (2%)
Fibrous osteodystrophy				1 (2%)
Bone, sternum	(48)	(4)	(1)	(48)
Autolysis				1 (2%)
Fibrous osteodystrophy	2 (4%)			2 (4%)
Osteopetrosis	1 (2%)			
Skeletal muscle	(48)	(4)	(1)	(48)
Autolysis				2 (4%)
Infiltration cellular, lymphocytic				1 (2%)
Polyarteritis				1 (2%)

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	Vehicle Control	25 mg/kg	50 mg/kg	100 mg/kg
2-Year Study (continued)				
Nervous System				
Brain, cerebellum	(48)	(4)	(1)	(48)
Autolysis				1 (2%)
Brain, cerebrum	(48)	(4)	(1)	(47)
Hydrocephalus		1 (25%)		
Infiltration cellular, lymphocytic, lateral ventricle	1 (2%)			
Mineralization, thalamus	19 (40%)	2 (50%)		19 (40%)
Peripheral nerve	(48)	(4)	(1)	(47)
Autolysis				2 (4%)
Degeneration				1 (2%)
Spinal cord	(48)	(3)	(1)	(48)
Autolysis				1 (2%)
Respiratory System				
Larynx	(46)	(4)	(1)	(48)
Autolysis				2 (2%)
Lung	(48)	(6)	(5)	(48)
Atelectasis	1 (2%)			
Autolysis				1 (2%)
Granuloma, focal	1 (2%)			
Hemorrhage, focal, right, apical lobe, sub pleura			1 (20%)	
Hemorrhage	1 (2%)			
Hyperplasia, alveolar epithelium	1 (2%)			5 (10%)
Infiltration cellular, lymphocytic	3 (6%)			2 (4%)
Nose	(48)	(4)	(1)	(48)
Autolysis				1 (2%)
Granuloma				1 (2%)
Trachea	(47)	(4)	(1)	(48)
Autolysis				2 (4%)
Special Senses System				
Eye	(48)	(4)	(1)	(47)
Autolysis				1 (2%)
Harderian gland	(48)	(8)	(2)	(48)
Autolysis				3 (6%)
Hyperplasia, unilateral	1 (2%)			2 (4%)
Infiltration cellular, lymphocytic				2 (4%)
Lacrimal gland	(47)	(4)	(1)	(46)
Atrophy, focal				1 (2%)
Autolysis				2 (4%)
Infiltration cellular, lymphocytic	1 (2%)			
Zymbal's gland	(47)	(3)	(1)	(47)
Autolysis				2 (4%)

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	Vehicle Control	25 mg/kg	50 mg/kg	100 mg/kg
2-Year Study (continued)				
Urinary System				
Kidney	(48)	(4)	(1)	(47)
Accumulation hyaline droplet, renal tubule	1 (2%)			2 (4%)
Autolysis				2 (4%)
Cyst, renal tubule	1 (2%)			
Degeneration, renal tubule	1 (2%)			4 (9%)
Glomerulosclerosis	2 (4%)			3 (6%)
Hyperplasia, focal, unilateral, renal tubule	1 (2%)			
Infarct, unilateral		1 (25%)		
Infiltration cellular, lymphocytic	1 (2%)			1 (2%)
Mineralization, renal tubule	1 (2%)			
Nephropathy	1 (2%)			
Regeneration, renal tubule	2 (4%)			4 (9%)
Urinary bladder	(48)	(4)	(1)	(48)
Autolysis				4 (8%)
Infiltration cellular, lymphocytic	1 (2%)			